

Amendments to the Claims

1. (Currently amended) A multiparticulate controlled release selective serotonin reuptake inhibitor (SSRI) composition ~~formulation~~ for oral administration, the multiparticulate composition ~~said formulation~~ comprising:
one or more quantities of particles, each of the particles comprising
 - (i) an inert non-pareil core,
 - (ii) an SSRI layer comprising ~~the cores of which comprise an SSRI~~
~~which is~~ fluvoxamine or a pharmaceutically-acceptable salt thereof disposed over the inert core, and, said core having
thereon
 - (iii) a rate-controlling membrane coating disposed over the SSRI layer,wherein the composition ~~which~~ allows the controlled release of the fluvoxamine ~~said~~
~~SSRI~~ over a period of not less than about 12 hours following oral administration.
2. (Canceled)
3. (Canceled)
4. (Currently Amended) The A composition ~~formulation~~ according to Claim 1, wherein the rate-controlling membrane coating comprises a mixture of ~~a major proportion of a~~ pharmaceutically acceptable film-forming, water-insoluble polymers ~~polymer and a~~
~~minor proportion of a pharmaceutically acceptable film-forming, water-soluble~~
~~polymer~~ in a selected ratio, ~~the selected ratio of said water-insoluble polymer to said~~
~~water-soluble polymer being~~ effective to permit a SSRI release rate which allows the
controlled release of the fluvoxamine from the composition ~~said SSRI~~ over a period of not less than about 12 hours following oral administration.
5. (Currently Amended) The A composition ~~formulation~~ according to Claim 1, wherein

the rate-controlling membrane coating comprises ~~contains~~ an ammonio methacrylate co-polymer.

Claims 6 to 19 (Canceled)

20. (Currently Amended) The A composition ~~formulation~~ according to Claim 1, wherein the SSRI layer ~~core~~ further comprises an organic acid, the fluvoxamine SSRI ~~component~~ and the organic acid being present in a ratio of from 50:1 to 1:50.

21. (Canceled)

22. (Canceled)

23. (Currently Amended) The A composition ~~formulation~~ according to Claim 1, wherein the said membrane coating comprises an ammonio methacrylate copolymer and a plasticizer, the combined amount of the said ammonio methacrylate copolymer and the said plasticizer in the said membrane coating being in an amount of from about 4% to about 15% of the weight of the particle cores ~~present in said formulation~~, and wherein the fluvoxamine SSRI release rate from the composition ~~particles~~ exhibits the following *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

- (a) no more than about 15% of the total fluvoxamine SSRI is released after 0.5 of an hour of measurement in the said apparatus;
- (b) no more than about 25% of the total fluvoxamine SSRI is released after 1 hour of measurement in the said apparatus;
- (c) between about 20% and about 75% of the total fluvoxamine SSRI is released

after 2 hours of measurement in the said apparatus;

- (d) not less than about 75% of the total fluvoxamine SSRI is released after 4 hours of measurement in the said apparatus; and
- (e) not less than about 85% of the total fluvoxamine SSRI is released after 6 hours of measurement in the said apparatus.

24. (Currently Amended) The A composition formulation according to Claim 1, wherein the said membrane coating comprises an ammonio methacrylate copolymer and a plasticizer, the combined amount of the said ammonio methacrylate copolymer and the said plasticizer in the said membrane coating being in an amount of from about 4% to about 15% of the weight of the particle cores present in said formulation, and wherein the fluvoxamine SSRI release rate from the composition particles exhibits the following *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

- (a) no more than about 20% of the total fluvoxamine SSRI is released after 4 hours of measurement in the said apparatus;
- (b) no more than about 45% of the total fluvoxamine SSRI is released after 6 hours of measurement in the said apparatus;
- (c) between about 45% and 80% of the total fluvoxamine SSRI is released after 8 hours of measurement in the said apparatus;
- (d) not less than about 70% of the total fluvoxamine SSRI is released after 10 hours of measurement in the said apparatus; and
- (e) not less than about 80% of the total fluvoxamine SSRI is released after 12

hours of measurement in the said apparatus.

25. (Canceled)
26. (Currently Amended) The A composition ~~formulation~~ according to Claim 1 wherein the composition comprises a first and second quantity of particles, the first quantity of particles defined by a first amount of rate-controlling membrane coating disposed over the SSRI layer and the second quantity of particles defined by a second amount of rate-controlling membrane coating disposed over the SSRI layer, wherein the first amount is different from the second amount in a form suitable for oral administration and comprising a blend of said particles in admixture with an immediate release form of SSRI or a pharmaceutically acceptable salt thereof to ensure a rapid attainment of effective therapeutic blood levels.
27. (Canceled)
28. (Currently Amended) The A composition ~~formulation~~ according to Claim 1 25, wherein the said membrane coating comprises an ammonio methacrylate copolymer and a plasticizer, the combined amount of the said ammonio methacrylate copolymer and the said plasticizer in said membrane coating being in an amount of from about 4% to about 15% of the weight of the particle ~~cores present in said formulation~~, and wherein the fluvoxamine SSRI release rate from the composition when measured *in vitro* using a USP type II dissolution apparatus (paddle) according to US Pharmacopoeia XXII in 0.05 M phosphate buffer at pH 6.8 substantially corresponds to the following dissolution pattern:
- (a) no more than 20% of the total fluvoxamine SSRI is released after 1 hour of measurement in the said apparatus;
- (b) no more than 60% of the total fluvoxamine SSRI is released after 2 hours of measurement in the said apparatus;

- (c) not less than 20% of the total fluvoxamine ~~SSRI~~ is released after 4 hours of measurement in the said apparatus;
 - (d) not less than 35% of the total fluvoxamine ~~SSRI~~ is released after 6 hours of measurement in the said apparatus;
 - (e) not less than 50% of the total fluvoxamine ~~SSRI~~ is released after 8 hours of measurement in the said apparatus;
 - (f) not less than 70% of the total fluvoxamine ~~SSRI~~ is released after 10 hours of measurement in the said apparatus; and
 - (g) not less than 75% of the total fluvoxamine ~~SSRI~~ is released after 12 hours of measurement in the said apparatus.
29. (Currently Amended) The A composition ~~formulation~~ according to Claim 1 ~~25~~, wherein the said membrane coating comprises an ammonio methacrylate copolymer and a plasticizer, the combined amount of the said ammonio methacrylate copolymer and the said plasticizer in the said membrane coating being in an amount of from about 4% to about 15% of the weight of the particle ~~cores present in said formulation~~, and wherein the fluvoxamine ~~SSRI~~ release rate from the composition ~~particles~~ exhibits the following *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:
- (a) no more than about 20% of the total fluvoxamine ~~SSRI~~ is released after 1 hour of measurement in the said apparatus;
 - (b) no more than about 45% of the total fluvoxamine ~~SSRI~~ is released after 2 hours of measurement in the said apparatus;

- (c) between about 20% and about 70% of the total fluvoxamine SSRI is released after 4 hours of measurement in the said apparatus;
 - (d) between about 35% and about 85% of the total fluvoxamine SSRI is released after 6 hours of measurement in the said apparatus;
 - (e) not less than about 50% of the total fluvoxamine SSRI is released after 8 hours of measurement in the said apparatus;
 - (f) not less than about 70% of the total fluvoxamine SSRI is released after 10 hours of measurement in the said apparatus; and
 - (g) not less than about 75% of the total fluvoxamine SSRI is released after 12 hours of measurement in the said apparatus.
30. (Currently Amended) The A composition formulation according to Claim 1, wherein the said membrane coating comprises an ammonio methacrylate copolymer and a plasticizer, the combined amount of the said ammonio methacrylate copolymer and the said plasticizer in the said membrane coating being in an amount of from about 4% to about 15% of the weight of the particles cores present in said formulation, and wherein the fluvoxamine SSRI release rate from the composition particles exhibits the following *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:
- (a) no more than about 50% of the total fluvoxamine SSRI is released after 2 hours of measurement in the said apparatus;
 - (b) not less than about 35% of the total fluvoxamine SSRI is released after 6 hours of measurement in the said apparatus; and

- (c) not less than about 80% of the total fluvoxamine ~~SSRI~~ is released after 22 hours of measurement in the said apparatus.

31. (Canceled)

32. (Canceled)

33. (Currently Amended) A method for the treatment of depression or obsessive compulsive disorder treatable with an SSRI, comprising administering to a patient suffering from one of the said conditions a therapeutically effective amount of a multiparticulate controlled release selective serotonin reuptake inhibitor (SSRI) composition for oral administration, the multiparticulate composition comprising one or more quantities of particles, each of the particles comprise:

an inert non-pareil core,

an SSRI layer comprising fluvoxamine or a pharmaceutically-acceptable salt thereof disposed over the inert core, and

a rate-controlling membrane coating disposed over the SSRI layer,

wherein the composition allows the controlled release of fluvoxamine over a period of not

less than about 12 hours following oral administration ~~SSRI formulation according to Claim 1.~~

34. (Currently Amended) The A method according to claim 33, wherein the fluvoxamine release rate from the composition exhibits the following *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 15% of the total fluvoxamine is released after 0.5 of an hour of measurement in the apparatus;

(b) no more than about 25% of the total fluvoxamine is released after 1

hour of measurement in the apparatus;

(c) between about 20% and about 75% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;

(d) not less than about 75% of the total fluvoxamine is released after 4 hours of measurement in the apparatus; and

(e) not less than about 85% of the total fluvoxamine is released after 6 hours of measurement in the apparatus for the treatment of depression or obsessive compulsive disorder treatable with an SSRI, comprising administering to a patient suffering from one of said conditions a therapeutically effective amount of a multiparticulate controlled release SSRI formulation according to Claim 24.

35. (Canceled)

36. (Currently Amended) The composition ~~formulation~~ according to Claim 1, wherein the ~~said~~ rate controlling polymer is fluvoxamine ~~SSRI~~-permeable.

37. (Currently Amended) The composition ~~formulation~~ according to Claim 1, wherein the ~~said~~ rate controlling polymer is fluvoxamine ~~SSRI~~-permeable and water soluble.

38. (Currently Amended) The composition ~~formulation~~ according to Claim 1, wherein the ~~said~~ rate controlling polymer is fluvoxamine ~~SSRI~~-permeable and water insoluble.

39. (Currently Amended) The composition ~~formulation~~ according to Claim 24 25, wherein the ~~said~~ formulation is in capsule form.

40. (Currently Amended) The composition ~~formulation~~ according to Claim 24 25, wherein the ~~said~~ formulation is in tablet form.

Claims 41 to 44 (Canceled)

45. (Currently Amended) The A method according to claim 33, wherein the fluvoxamine release rate from the composition exhibits the following *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 20% of the total fluvoxamine is released after 4 hours of measurement in the apparatus;

(b) no more than about 45% of the total fluvoxamine is released after 6 hours of measurement in the apparatus;

(c) between about 45% and 80% of the total fluvoxamine is released after 8 hours of measurement in the apparatus;

(d) not less than about 70% of the total fluvoxamine is released after 10 hours of measurement in the apparatus; and

(e) not less than about 80% of the total fluvoxamine is released after 12 hours of measurement in the apparatus ~~for the treatment of depression or obsessive compulsive disorder treatable with an SSRI, comprising administering to a patient suffering from one of said conditions a therapeutically effective amount of a multiparticulate controlled release SSRI formulation according to Claim 24.~~

46. (Canceled)

47. (Currently Amended) A multiparticulate controlled release selective serotonin reuptake inhibitor (SSRI) composition ~~formulation~~ for oral administration comprising two quantities of particles, each of the particles comprising

(i) an inert non-pareil core,

(ii) an SSRI layer comprising fluvoxamine or a pharmaceutically-

acceptable salt thereof disposed over the inert core, and

(iii) ~~, which comprises particles, the core of which comprises an SSRI which is fluvoxamine or a pharmaceutically acceptable salt thereof, said core coated with a coating of a rate-controlling polymeric acrylate, or methacrylate lacquer, or a mixture thereof disposed over the fluvoxamine,~~

wherein the composition substance which allows the controlled release of the fluvoxamine said SSRI over a period of not less than about 12 hours following oral administration, and

wherein the rate-controlling polymeric acrylate or methacrylate lacquer coating of the first quantity of particles is present in a first amount, and the rate-controlling polymeric acrylate or methacrylate lacquer coating of the second quantity of particles is present in a second amount that is different from the first amount.

48. (Currently Amended) ~~The A composition formulation~~ according to Claim 47 wherein the coating said substance is the polymeric said acrylate lacquer.
49. (Currently Amended) ~~The A composition formulation~~ according to Claim 47 wherein the coating said substance is the said methacrylate lacquer.
50. (Currently Amended) ~~The A composition formulation~~ according to Claim 47 wherein the coating said substance is a lacquer which contains a mixture of said acrylate and methacrylate.
51. (Currently Amended) ~~The A composition formulation~~ according to Claim 47 wherein the coating said substance is an acrylic resin comprising a copolymer of acrylic and methacrylic acid esters having a low content of quaternary ammonium groups.

Claims 52 to 54 (Canceled)

55. (Currently Amended) The composition formulation of Claim 47 wherein the rate-controlling said membrane coating comprises an ammonio methacrylate lacquer

~~copolymer~~ and a plasticizer, the combined amount of the said ammonio methacrylate lacquer copolymer and the said plasticizer in the said membrane coating being in an amount of from about 4% to about 15% of the weight of the particle cores present in said formulation.

56. (Currently Amended) The composition formulation of Claim 55 wherein the combined amount of the said ammonio methacrylate lacquer copolymer and the said plasticizer in the rate controlling coating of the first or second quantity of particles said membrane coating is in an amount of 4%, 6%, 8%, 10%, 12%, or 15% of the weight of the particle cores present in said formulation.

57. (Currently Amended) A method for the treatment of depression or obsessive compulsive disorder treatable with an SSRI, comprising administering to a patient suffering from one of the said conditions a therapeutically effective amount of a multiparticulate controlled release selective serotonin reuptake inhibitor (SSRI) composition for oral administration comprising two quantities of particles, each of the particles comprise

(i) an inert non-pareil core,

(ii) an SSRI layer comprising fluvoxamine or a pharmaceutically-acceptable salt thereof disposed over the inert core, and

(iii) a coating of a rate-controlling polymeric acrylate, methacrylate lacquer, or a mixture thereof disposed over the fluvoxamine,

wherein the composition allows the controlled release of the fluvoxamine over a period of not less than about 12 hours following oral administration, and wherein the rate-controlling polymeric acrylate or methacrylate lacquer coating of the first quantity of particles is present in a first amount, and the rate-controlling polymeric acrylate or methacrylate lacquer coating of the second quantity of particles is present in a second amount that is different from the first amount ~~SSRI formulation according to Claim 55.~~

58. (Canceled)

59. (Currently Amended) A unit dose formulation which is effective in supplying fluvoxamine to the blood of a patient such that, following a single application of the unit dose to the patient, the amount of circulating fluvoxamine (AUC_{0-4}) in the blood serum of the patient is about 128 to about 1,900 ng/ml.h, the said formulation comprising one or more quantities of particles, the cores of which comprise an SSRI which is each particle comprising fluvoxamine or a pharmaceutically-acceptable salt thereof and, said core having thereon a rate-controlling membrane coating disposed over the fluvoxamine, wherein the composition which allows the controlled release of the fluvoxamine said SSRI over a period of not less than about 12 hours following oral administration.
60. (Currently Amended) The formulation of Claim 59 wherein the said membrane coating comprises an ammonio methacrylate copolymer and a plasticizer, the combined amount of the said ammonio methacrylate copolymer and the said plasticizer in the said membrane coating being in an amount of from about 4% to about 15% of the weight of the particle cores present in said formulation.
61. (Currently Amended) The formulation of Claim 60 wherein the combined amount of the said ammonio methacrylate copolymer and the said plasticizer in the said membrane coating is in an amount of 4%, 6%, 8%, 10%, 12%, or 15% of the weight of the particles cores present in said formulation.
62. (Currently Amended) The composition formulation of Claim 47 58 wherein the controlled-release of the fluvoxamine is effective in supplying fluvoxamine to the blood of a patient such that, following a single application of the composition to the patient, the said amount of circulating fluvoxamine (AUC_{0-4}) in the blood serum of the patient is about 128 to about 1,175 ng/ml.h.
63. to 66. (Canceled)
67. (New) A composition according to claim 1, wherein the rate-controlling membrane

coating comprises an ammonio methacrylate copolymer having 12.5% polymer solids and dibutyl sebacate.

68. (New) A method according to claim 33, wherein the fluvoxamine release rate from the composition exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 20% of the total fluvoxamine is released after 1 hour of measurement in the apparatus;

(b) no more than about 45% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;

(c) between about 20% and about 70% of the total fluvoxamine is released after 4 hours of measurement in the apparatus;

(d) between about 35% and about 85% of the total fluvoxamine is released after 6 hours of measurement in the apparatus;

(e) not less than about 50% of the total fluvoxamine is released after 8 hours of measurement in the apparatus;

(f) not less than about 70% of the total fluvoxamine is released after 10 hours of measurement in the apparatus; and

(g) not less than about 75% of the total fluvoxamine is released after 12 hours of measurement in the apparatus.

69. (New) A method according to claim 33, wherein the fluvoxamine release rate from the composition exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M

phosphate buffer at pH 6.8:

- (a) no more than about 20% of the total fluvoxamine is released after 1 hour of measurement in the apparatus;
- (b) no more than about 45% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;
- (c) between about 20% and about 70% of the total fluvoxamine is released after 4 hours of measurement in the apparatus;
- (d) between about 35% and about 85% of the total fluvoxamine is released after 6 hours of measurement in the apparatus;
- (e) not less than about 50% of the total fluvoxamine is released after 8 hours of measurement in the apparatus;
- (f) not less than about 70% of the total fluvoxamine is released after 10 hours of measurement in the apparatus; and
- (g) not less than about 75% of the total fluvoxamine is released after 12 hours of measurement in the apparatus.

70. (New) A method according to claim 33, wherein the fluvoxamine release rate of the composition exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

- (a) no more than about 50% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;
- (b) not less than about 35% of the total fluvoxamine is released after 6 hours of measurement in the apparatus; and

(c) not less than about 80% of the total fluvoxamine is released after 22 hours of measurement in the apparatus.

71. (New) The composition of Claim 1, wherein the release of fluvoxamine is effective in supplying fluvoxamine to the blood of a patient such that, following a single application of the composition to the patient, the amount of circulating fluvoxamine (AUC_{0-4}) in the blood serum of the patient is about 128 to about 1,175 ng/ml.h.

72. (New) The composition of claim 47, wherein the fluvoxamine release rate from the composition exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 15% of the total fluvoxamine is released after 0.5 of an hour of measurement in the apparatus;

(b) no more than about 25% of the total fluvoxamine is released after 1 hour of measurement in the apparatus;

(c) between about 20% and about 75% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;

(d) not less than about 75% of the total fluvoxamine is released after 4 hours of measurement in the apparatus; and

(e) not less than about 85% of the total fluvoxamine is released after 6 hours of measurement in the apparatus.

73. (New) The composition of claim 47, wherein the fluvoxamine release rate from the composition exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M

phosphate buffer at pH 6.8:

- (a) no more than about 20% of the total fluvoxamine is released after 4 hours of measurement in the apparatus;
- (b) no more than about 45% of the total fluvoxamine is released after 6 hours of measurement in the apparatus;
- (c) between about 45% and 80% of the total fluvoxamine is released after 8 hours of measurement in the apparatus;
- (d) not less than about 70% of the total fluvoxamine is released after 10 hours of measurement in the apparatus; and
- (e) not less than about 80% of the total fluvoxamine is released after 12 hours of measurement in the apparatus.

74. (New) The composition of claim 47, wherein the fluvoxamine release rate from the composition exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

- (a) no more than 20% of the total fluvoxamine is released after 1 hour of measurement in the apparatus;
- (b) no more than 60% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;
- (c) not less than 20% of the total fluvoxamine is released after 4 hours of measurement in the apparatus;
- (d) not less than 35% of the total fluvoxamine is released after 6 hours of measurement in the apparatus;

(e) not less than 50% of the total fluvoxamine is released after 8 hours of measurement in the apparatus;

(f) not less than 70% of the total fluvoxamine is released after 10 hours of measurement in the apparatus; and

(g) not less than 75% of the total fluvoxamine is released after 12 hours of measurement in the apparatus.

75. (New) The composition of claim 47, wherein the fluvoxamine release rate from the composition exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 20% of the total fluvoxamine is released after 1 hour of measurement in the apparatus;

(b) no more than about 45% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;

(c) between about 20% and about 70% of the total fluvoxamine is released after 4 hours of measurement in the apparatus;

(d) between about 35% and about 85% of the total fluvoxamine is released after 6 hours of measurement in the apparatus;

(e) not less than about 50% of the total fluvoxamine is released after 8 hours of measurement in the apparatus;

(f) not less than about 70% of the total fluvoxamine is released after 10 hours of measurement in the apparatus; and

(g) not less than about 75% of the total fluvoxamine is released after 12 hours of measurement in the apparatus.

76. (New) The composition of claim 47, wherein the fluvoxamine release rate from the composition exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 50% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;

(b) not less than about 35% of the total fluvoxamine is released after 6 hours of measurement in the apparatus; and

(c) not less than about 80% of the total fluvoxamine is released after 22 hours of measurement in the apparatus.

77. (New) The unit dose formulation of claim 59, wherein the fluvoxamine release rate from the formulation exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 15% of the total fluvoxamine is released after 0.5 of an hour of measurement in the apparatus;

(b) no more than about 25% of the total fluvoxamine is released after 1 hour of measurement in the apparatus;

(c) between about 20% and about 75% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;

(d) not less than about 75% of the total fluvoxamine is released after 4 hours of measurement in the apparatus; and

(e) not less than about 85% of the total fluvoxamine is released after 6 hours of measurement in the apparatus.

78. (New) The unit dose formulation of claim 59, wherein the fluvoxamine release rate from the formulation exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 20% of the total fluvoxamine is released after 4 hours of measurement in the apparatus;

(b) no more than about 45% of the total fluvoxamine is released after 6 hours of measurement in the apparatus;

(c) between about 45% and 80% of the total fluvoxamine is released after 8 hours of measurement in the apparatus;

(d) not less than about 70% of the total fluvoxamine is released after 10 hours of measurement in the apparatus; and

(e) not less than about 80% of the total fluvoxamine is released after 12 hours of measurement in the apparatus.

79. (New) The unit dose formulation of claim 59, wherein the fluvoxamine release rate from the formulation exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than 20% of the total fluvoxamine is released after 1 hour of measurement in the apparatus;

(b) no more than 60% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;

(c) not less than 20% of the total fluvoxamine is released after 4 hours of measurement in the apparatus;

(d) not less than 35% of the total fluvoxamine is released after 6 hours of measurement in the apparatus;

(e) not less than 50% of the total fluvoxamine is released after 8 hours of measurement in the apparatus;

(f) not less than 70% of the total fluvoxamine is released after 10 hours of measurement in the apparatus; and

(g) not less than 75% of the total fluvoxamine is released after 12 hours of measurement in the apparatus.

80. (New) The unit dose formulation of claim 59, wherein the fluvoxamine release rate from the formulation exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 20% of the total fluvoxamine is released after 1 hour of measurement in the apparatus;

(b) no more than about 45% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;

(c) between about 20% and about 70% of the total fluvoxamine is released after 4 hours of measurement in the apparatus;

(d) between about 35% and about 85% of the total fluvoxamine is released after 6 hours of measurement in the apparatus;

(e) not less than about 50% of the total fluvoxamine is released after 8 hours of measurement in the apparatus;

(f) not less than about 70% of the total fluvoxamine is released after 10 hours of measurement in the apparatus; and

(g) not less than about 75% of the total fluvoxamine is released after 12 hours of measurement in the apparatus.

81. (New) The unit dose formulation of claim 59, wherein the fluvoxamine release rate from the formulation exhibits the following in vitro dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 50% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;

(b) not less than about 35% of the total fluvoxamine is released after 6 hours of measurement in the apparatus; and

(c) not less than about 80% of the total fluvoxamine is released after 22 hours of measurement in the apparatus.